

b.) Remarks

The claims have been amended in order to recite the present invention with the specificity required by statute. The subject matter of the amendment is disclosed in the specification as filed, *inter alia*, at page 13, line 9 to page 14, line 4, and in Example 5 at pages 29-30, etc. Accordingly, no new matter has been added.

Claims 30, 37, 43, 44 and 49 are rejected under 35 U.S.C. §101 because the claimed invention is directed to non-statutory subject matter. As to claims 30, 37 and 49 at least, this rejection is not well-understood; the MPEP explicitly authorizes use of “isolated” to distinguish naturally occurring products. Nonetheless, solely in order to expedite matters, all claims have been amended to even more clearly recite plainly statutory subject matter.

Claims 6, 16, 24, 31, 38 and 50 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter of the present invention. In response, all claims have been amended as kindly suggested by the Examiner to specify agent, compositions or methods obtained by extracting plants with aqueous medium to obtain an extract, and obtaining a filtrate by extracting that extract with alcohol or water containing alcohol. Claims 30, 37, 43 and 49 are amended similarly.

Claims 6, 16, 24, 31, 38 and 50 stand rejected under 35 U.S.C. 102(e) as anticipated by Konishi (U.S. Patent No. 6,541,041).

This rejection is respectfully traversed. However, prior to setting forth their bases for traversal, Applicants would like to briefly point out the salient features of the present invention and, *inter alia*, its patentable nature over the prior art. Specifically, the subject matter of these claims relates to a liver function protecting or improving agent

(claim 6), a food, drink or feed (claims 16, 24 and 50) or an additive (claims 31 and 38) which comprises a particular active ingredient, namely a filtrate obtained by

- (i) extracting a plant of the family *Saxifragaceae* with an aqueous medium and
- (ii) extracting the product of (i) with alcohol (or water containing alcohol).

This subject matter is not disclosed by Konishi.

Konishi describes extracts containing soluble silicon compounds obtained by subjecting plants including *Saxifraga stolonifera* to extraction with water or aqueous solvent. However, Konishi does not relate to a filtrate obtained by extracting that extract residue with alcohol or water containing alcohol. Accordingly, the subject matter of these claims cannot be anticipated by the prior art.

Claims 6, 16, 24, 31, 38, 43 and 44 are rejected under 35 U.S.C. 103(a) as being obvious over Fuji Rebio (XP002220392) in view of Konishi.

The subject matter of claims 6, 16, 24, 31 and 38 is discussed above.

Amended claims 43 and 44 recite all those features and more.

Fuji Rebio describes that tannins purified from *Saxifragasto lonifera* can be used for treatment of hepatitis B. However, no method for purifying tannin is described in Fuji Rebio. Accordingly, even taken with Konishi (which, as discussed above, also fails to disclose a two-stage extraction using aqueous and alcoholic media), there is simply no *prima facie* obviousness.

Lastly, claims 30, 37, 43, 44 and 49 are rejected under 35 U.S.C. 103(a) as being obvious over Yamahara (XP002220391) in view of Levinson (U.S. Patent No. 6,479,545). This rejection is respectfully traversed as well.

As the Examiner is well-aware, the subject matter of amended claims 30, 37 and 49 relate to liver function protecting or improving agents obtained by extracting an

extract residue with alcohol (or water containing alcohol), wherein the extract residue is obtained by extracting a plant of *Hydrangea Dulcis Folium* with an aqueous medium. Amended claims 43 and 44 relate to agents similarly obtained from a plant of the family of *Saxifragaceae*. The subject matter of these claims is not disclosed by Yamahara and Levinson, whether taken singly or together.

Yamahara describes a methanol extract of *Hydrangea macrophylla* Seringe var. *Thunbergii* Makino that may be cholagoic. However, Yamahara does not teach (i) any filtrate obtained by extracting with alcohol an extract residue, wherein that extract residue is obtained by extraction with an aqueous medium, let alone (ii) that such protects or improves liver function.

Levinson describes that compositions comprising an extract of hydrangea may be administered orally to humans and animals in various forms. However, Levinson does not relate to an alcohol extract obtained from a residue of a water extraction^{1/} of hydrangea.

A salient feature of the present invention is:

- extracting with an aqueous medium a plant of *Saxifragaceae* or *Hydrangea* to obtain an extract residue (e.g., a first extraction)
- extracting the extract residue with alcohol or water containing alcohol (e.g., a second extraction).

In this regard, Applicants also wish to point out that their combination of two disparate extractions results in markedly greater liver function protection or improvement compared with an extract obtained by a one-step extraction. This is evidenced by the data already of record.

^{1/} Not to mention that claims 43 and 44 recite that the plants are *Saxifragaceae*.

For instance, Example 16 of the present application evaluates the inhibiting activity of one-step extracts of Hydrangeae Dulcis Folium on D-galactosamine-induced rat hepatopathy (“GTP activity”) using the feeds of Examples 7, 9 and 8. These feeds respectively contain 3% freeze-dried powders of the water extract obtained in Example 1, the hot water extract obtained in Example 4 and the 60% ethanol extract obtained in Example 2. On the other hand, the feed of Example 10 contains 1% freeze-dried powder of a two-step extract according to the present invention, e.g., a 60% ethanol extract of the residue of a water extract of Hydrangeae Dulcis Folium. As apparent from Table 1 at specification page 36, the GTP activity of Example 10 according to the present invention is 200-350 percent better inhibited than the feeds of Examples 7-9 according to the closest prior art.

This remarkable improvement is of clear utility to those of ordinary skill and is entirely unobvious in view of the prior art.

Accordingly, while Applicants respectfully submit there is no *prima facie* obviousness, it is clear that any *prima facie* obviousness is rebutted on the record.

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 6, 16, 24, 30, 31, 37, 38, 43, 44, 49, 50 and 52-58 remain presented for continued prosecution.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,


Attorney for Applicants
Lawrence S. Perry
Registration No. 31,865

FITZPATRICK, CELLA, HARPER & SCINTO
30 Rockefeller Plaza
New York, New York 10112-3801
Facsimile: (212) 218-2200

LSP\ac

NY_MAIN 452292v1